

JUN 23 2008

## 5 10(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K073280

**Submitter:**

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● **Contact Person:**

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● **Date Prepared:**

November 8, 2007

**Name of the devices:**

- **Trade/Proprietary Name:** BeneView T Series patient monitors (Including Models BeneView T8, BeneView T6 and BeneView T5)

- **Common Name:** Patient Monitor

● **Classification**

21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardiometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers –	Class II

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	Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1500	Enflurane gas analyzer	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II
21 CFR 882.1400	Electroencephalograph	Class II
21 CFR 870.2770	Impedance plethysmograph	Class II

#### Legally Marketed Predicate Devices:

- 1) K070791, PM-9000 Express Patient Monitor, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
- 2) K041294, BioZDx Hemodynamic Monitor, Cardiodynamics International Corp.
- 3) K040183, BISX, ASPECT MEDICAL SYSTEMS, INC.
- 4) K042601, CAPNOSTAT 5, RESPIRONICS NOVAMETRIX, INC.
- 5) K041790, DATEX-OHMEDA S/5 COMPACT ANESTHESIA MONITOR with datex-ohmeda

#### Description:

The BeneView T Series patient monitors (including models BeneView T8, T6 and T5) are Mindray's new generation monitoring product family with ergonomic and flexible design in platform of both software and hardware to meet the clinical needs of standard vital signs, high-acuity and anesthesia monitoring.

BeneView T8, BeneView T6 and BeneView T5 have same design principle and technical characteristics:

- Same system framework and components.
- Same Hardware design principle in main unit.
- Same parameters measurement subsystems (including parameters modules and accessories).
- Same peripheral equipments or accessories (including mouse, keyboard and printer, etc.)
- Same host software and modules software.

The difference between BeneView T8 and BeneView T6 is the size of display screen. And the differences between BeneView T8 and BeneView T5 are the appearance and interior structure in main unit.

**Statement of intended Use:**

The BeneView T Series patient monitors including models BeneView T8, BeneView T6 and BeneView T5 are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESPIR), Temperature (TEMP), Pulse Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), carbon dioxide (CO<sub>2</sub>), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS) and respiration mechanics (RM).

The arrhythmia detection, ST Segment analysis, BIS and RM monitoring are not intended for neonatal patients. The ICG is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 159kg. Other parameters can be applied to a single adult, pediatric or neonatal patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport, hospital ambulance, or home use.

**Comparison of Technological Characteristics:**

Both the subject devices and the predicate devices provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms.

The specifications and technologies for parameters including ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESPIR), Temperature (TEMP), Pulse Oxygen Saturation (SpO<sub>2</sub>), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), Pulse Rate(PR), Carbon Dioxide (CO<sub>2</sub>, for Oridion MiniMediCO<sub>2</sub> and Mindray CO<sub>2</sub> Module) and anesthetic gas (AG) of the device are substantial equivalent to the predicate devices, the cleared PM-9000 Express Patient Monitor (k070791).

The Bispectral Index (BIS), Impedance Cardiograph (ICG) and Carbon Dioxide (CO<sub>2</sub>) (for CAPNOSTAT mainstream CO<sub>2</sub> Module) parameter specifications and technologies are same to the predicate devices.

Both the subject device and the predicate device for RM parameter adopt the same measuring method using flow sensor, but have different parameter specifications. The technological differences do not affect the safety or efficacy of the devices.

**Testing:**

Any safety issues that may be raised by software controlled medical devices are addressed in the systems hazard analysis and in the system validation. And testing has been conducted to validate and verify that meet all design specifications.

The testing consisted of software testing, clinical and/or bench performance testing, biocompatibility testing/evaluation and safety/environmental/EMC testing. All environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. The BeneView T Series patient monitors including models BeneView T8, BeneView T6 and BeneView T5 have also been tested to assure compliance with the requirements of various published standards.

The conclusions drawn from the testing of the BeneView T Series patient monitors including models BeneView T8, BeneView T6 and BeneView T5 demonstrate that the devices are as safe and effective as the legally marketed predicate devices.

**Conclusion:**

The BeneView T Series patient monitors are substantially equivalent to currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 23 2008

Shenzhen Mindray Bio-Medical Electronics Co. Ltd.  
c/o Ms. Susan D. Goldstein-Falk  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
Great Neck, New York 11021

Re: K073280

Trade/Device Name: BeneView T Series Patient Monitor, including models BeneView T8, BeneView T6 and BeneView T5

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and alarm (including ST-segment measurement and alarm)

Regulatory Class: Class II (Two)

Product Code: MHX

Dated: June 4, 2008

Received: June 6, 2008

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

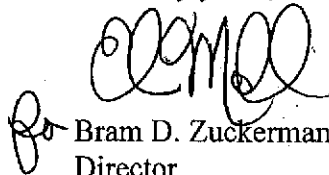
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Ms. Susan D. Goldstein-Falk

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K073280

Device Name: BeneView T Series patient monitors

(including models BeneView T8, BeneView T6 and BeneView T5)

### Indications for Use:

The BeneView T Series patient monitors including models BeneView T8, BeneView T6 and BeneView T5 are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESPIR), Temperature (TEMP), Pulse Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), carbon dioxide (CO<sub>2</sub>), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS) and respiration mechanics (RM).

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular Devices

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